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Washington, DC 20231

OFGS File No. : P/619-57
Inventor : Alexander BROCKHOFF
Title : METHOD AND DEVICE FOR REMOVING GAS FROM GAS CONTAINING BLOOD
Assignee : Kevin Business Corporation

Enclosed herewith please find the following documents in the above-identified application for United States Letters Patent:

13 Pages of Specification including Abstract and Claims
17 Numbered Claims Calculated as 17 Claims for Fee Purposes
1 Sheet of Drawing Containing Figure 1. (Formal)
X Declaration and Power of Attorney
X Priority is Claimed under 35 U.S.C. §119:
Convention Date 9 MAY 1997 for GERMAN Appln. S.N. 197 19 555.5
X Certified Priority Application
X Verified Statement Claiming Small Entity Status under 37 C.F.R. §1.27.
X Assignment and Conveyance Sheet
X Return-Addressed Post Card
OFGS Check No. 69788, which includes the fee of $425.00, calculated as follows:

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Additional Filing Fees:	
Total Number of Claims in Excess of 20, times $22:	
Number of Independent Claims in Excess of 3, times $80. . .	
One or More Multiple Dependent Claims: Total $260.	
Total Filing Fees or	
Total Filing Fee Reduced 50% for Small Entity:	$ 385.00
Assignment Recording Fee: $40	$ 40.00
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September 26, 1997
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Respectfully submitted,

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METHOD AND DEVICE FOR REMOVING GAS FROM GAS-CONTAINING BLOOD

BACKGROUND OF THE INVENTION

The present invention relates to a method and device for removing gas from gas containing blood by operation of a centrifuging device.

This type of device is disclosed in British A-2 063 108. Further devices for separating gas from gas containing blood are described in US Patents 3,785,380, 4,368,118, 4,388,922 and 5,451,321, as well as in German DE-C-36 24 363 and 36 41 644 and DE-A-43 29 385.

Blood given to a patient should not contain any air or other gas, even in the form of micro-small bubbles of gas. The blood is fed to the patient by a pressure pump. Although that is the preferred field of use of the invention, it does not exclude the invention also being used to remove air from blood which is drawn from a patient at the site of a wound, since it frequently cannot be avoided that air is also drawn into the bloodstream at the site of the wound. The air must be removed from the blood as rapidly as possible and as close as possible to the wound since it can otherwise damage the blood. Other possible fields of use of the invention are the removal of gas from gas-containing blood which is transported from one instrument to another or to a container.

SUMMARY OF THE INVENTION

The object of the invention is to improve the efficiency of the gas removal and, in particular, to

provide a method and a device with which even micro-small bubbles of gas can be removed from gas containing blood, even if the gas containing blood is being conveyed in a large volume per unit of time.

The invention concerns a method and device for removing gas from gas containing blood. A non-rotating cyclone eddy chamber has the blood circulating therein and centrifugal force separates the blood radially outward and the gas radially inward. The cyclone inlet comprises a blood inlet channel that extends in a helical circular form developed to narrow in funnel like manner in the direction of flow toward the cyclone eddy chamber to accelerate the blood flow entering that chamber tangentially. A gas outlet is arranged in the radially inner center of the cyclone eddy chamber path while the blood outlet is coaxial and outward of the gas outlet.

Other objects, features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawing.

BRIEF DESCRIPTION OF THE DRAWING

Fig. 1 diagrammatically shows, in part in axial section, a device in accordance with the invention for removing gas from gas containing blood.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 shows a source of blood 2, which may be a device known in medicine, for instance, a blood oxygenator, a heart-lung machine, a blood filter, a reservoir, a cardioplegia system, a plasmaphoresis system, a dialysis system, or some other blood transfusion system. The blood source is connected by a

pressure pump 4 to an input 6 of a cyclone, eddy current device 8 and conducts blood through the device 8 to a pressure 10 or an instrument. This instrument or the patient 10 is connected via a hose 12 to a cyclone outlet channel 14 of the cyclone eddy current device 8.

The cyclone eddy current device 8 contains, arranged coaxially one behind the other along a linear center axis 16, a housing 18 of circular cross section with its inlet 6 at one axial end and its outlet channel 14 on the other axial end. The housing inlet 6 has, arranged axially one behind the other, an inlet section 20 which widens in funnel like manner in the direction of flow, followed by a cylindrical channel section 22 and then by a cyclone eddy chamber section 24 which narrows down in a funnel like manner in the direction of flow and forms the circumferential wall of a cyclone eddy chamber 26 which narrows down in a funnel like manner in the same way. The gas containing mixture of blood rotates with constant direction of rotation within the cyclone eddy chamber 26 from the axial inlet starting point of the chamber to the axial outlet end of the chamber. Here, the mixture of blood and gas is separated by centrifugal force into a radially outer blood phase (blood portion) and a radially inner gas phase (gas portion). The downstream end 28 of the cyclone eddy chamber 26 is connected to the upstream starting point of the outlet channel 14 and forms a cyclone outlet for the blood phase.

Within the channel section 22 of the housing 18 and coaxial to the center axis 16, there is an insert body 30 which has at least one wider diameter helical rib 32. Between adjacent coils of the rib and the body 30, at least one helical groove 34 is formed. Together, the

surrounding wall of the housing, which the rib 32 engages, the groove or grooves 34 define a helical blood inlet channel 36. The blood inlet channel 36 extends from a point downstream of the inlet 6 up to the upstream starting point 38 of the cyclone eddy chamber 26 to there defines a substantially tangential cyclone inlet 40 from which the gas containing blood flows substantially tangentially into the cyclone eddy chamber 26. The blood then flows in a cyclone eddy current up to the end 28 of the chamber, and after passing that end and further rotating, it passes into the outlet channel 14. The cyclone eddy chamber 26 can be developed so as to narrow in funnel shape over its entire length, as shown in Fig. 1, or it may have a circular cylindrical shape, at least at its upstream initial section. The funnel like narrowing shape of the cyclone eddy chamber 26 is to maintain the cyclone centrifugal energy over the entire axial length of the cyclone eddy chamber 26.

The diameter 44 of the insert body 30 at the base of the grooves 34 is smallest at the upstream starting point 46 of a groove and increases downstream in the direction of flow up to the cyclone inlet 40, i.e., the diameter of the groove decreases and its volume decreases. The channel section 22 of the housing 18 which limits the grooves 34 at the outside circumference can have a shape other than circular cylindrical. In any event, it is so shaped that the helical blood inlet 36 defined by the ribs 22, the grooves 34 and the channel section 22 has, at least over a part of its length but preferably over its entire length, a flow cross section which becomes continuously smaller in funnel like manner in the direction of flow so that the gas containing blood

is accelerated downstream in it and flows with the greatest possible speed into the cyclone eddy chamber 26.

The ribs 32 can rest against the channel section 22 or be a small distance in from it. On its upstream starting point, the insert body 30 preferably has a conical tip 48 directed opposite the flow of blood. At its downstream end, the body 30 has a conical tip 50 directed narrower in the direction of flow. Instead of such conical tips 48 and 50, the insert body 90 may also have rounded or flat end surfaces.

The angles shown in the drawing have preferably the following size ranges: angle α between the center line 16 and a generatrix of the insert body 30 on the bottom of the grooves 34: 0° to 30°; angle β between the channel section 22 of the housing 18 and the cyclone eddy chamber section 24 of the housing 18: 0° to 45°; the angle γ between the center line 16 and an end of the rib 32 transverse to the center line 16: 45° to 80°, and the angle δ of the downstream conical tip 50 between the center line 16 and the generatrix of this conical tip 50: 90° to 15°. If the angle α between the center line 16 and the lengthwise line on the bottom of the grooves 34 is 0° or only a few degrees, then the lengthwise line of the channel section 22 should pass in the direction of flow of the blood obliquely to the center line 16 so that the grooves 34 of the blood inlet channel 36 have a cross sectional size which becomes narrower in wedge like manner in the direction of flow of the blood. As another possibility for developing the grooves 34 and thus also the blood inlet channel 36 in a manner which narrows down in funnel like manner in the direction of flow, the distance between the ribs 32 continuously decreases in the direction of flow. In these ways, the height and/or

width of the grooves 34 can be changed to gradually decrease the volume of the groove downstream.

The gas containing blood which enters tangentially into the cyclone eddy chamber 26 at the cyclone inlet 40 flows in the form of a cyclone eddy current, through the cyclone eddy chamber 26 to its outlet end 28. This produces centrifugal forces which force the blood phase or blood portion of the gas containing blood into the radially outer cyclone eddy current region. As the blood phase is heavier than the gas contained in the blood, this forces the gas or the gas phase into the radially inner cyclone eddy current region. The cyclone eddy current travels into the outlet channel 14.

Within the radially inner center of this cyclone eddy current, a gas outlet opening 16 is arranged coaxial to the center line and facing in the direction opposite the axial flow of the blood phase and the gas phase, so that the gas phase can flow only from a small cross-sectional region in and around the center line 16 into the gas outlet opening 60. The gas outlet opening 60 can, for instance, be arranged up to 10 cm downstream of the downstream end 28 of the cyclone eddy chamber 26, and this is shown by a gas line 62 arranged coaxially in the outlet channel 14 or at the downstream end 28, as shown in dashed line at 64, or even upstream of the end 28, as shown diagrammatically at 66. In all cases, the gas outlet opening 60 is located coaxially on the center line 16 and is directed opposite the axial direction of flow of the gas phase and the blood phase.

In the embodiment shown, the inlet 6, the eddy chamber 26, the outlet channel 14, the gas outlet opening 60, and at least the initial section of the gas line 62

within which the gas outlet opening 60 is formed are all arranged coaxial to the linear center line 16.

In a modified embodiment of the invention, the direction of the inlet 6 can lie in a region which is between an axial direction and a tangential direction to the center line 16, the tangential direction pointing in the same circumferential direction as the grooves 34, so that the flow of blood is not reversed when entering the chamber 26. Furthermore, the direction of the blood outlet channel 14 and/or the direction of the gas outlet opening 60 and of its gas line 62, or at least of the initial section of this gas line 62, can lie in a region between the axial forward direction in accordance with Fig. 1 and the tangential direction of movement of the cyclone eddy current.

Although the present invention has been described in relation to a particular embodiment thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

WHAT IS CLAIMED IS:

1. A method of removing gas from gas containing blood, comprising

introducing gas containing blood into a helical, circularly extending, gradually narrowing cross section, blood inlet channel and moving the blood through the narrowing cross section of the channel for accelerating the flow through the channel as the channel narrows;

introducing the accelerated blood flow into a following non-rotating cyclone eddy chamber at a rate sufficient for the blood phase of the gas containing blood to be urged into the radially outer region of the cyclone eddy chamber by centrifugal force and for the gas phase of the gas containing blood to be separated from the blood phase and to be urged into a radially inner region of the cyclone eddy chamber by the blood phase in that chamber;

discharging the blood phase and the gas phase separately from the cyclone eddy chamber after they have been separated from each other, wherein the gas phase is conducted from the radially inner center of the cyclone eddy current at a place located downstream of the blood inlet channel in a direction lying in the region between the axial forward direction and the tangential direction of movement of the cyclone eddy current of the blood in the cyclone eddy chamber.

2. The method of claim 1, further comprising forcing the gas containing blood with positive pressure through the blood inlet channel and into and through the cyclone eddy chamber.

3. A device for removing gas from gas containing blood, the device comprising:

a non-rotating cyclone eddy chamber shaped for passing gas containing blood in the form of a cyclone eddy current for producing a centrifugal force that separates the blood into a blood phase in the radially outer cyclone eddy region and a gas phase in the radially inner cyclone eddy current region;

a cyclone inlet to the cyclone eddy chamber for gas containing blood; the cyclone inlet comprising at least one helically circularly extending blood inlet channel shaped for narrowing in funnel like manner, at least over part of its length in the direction of flow of blood therealong, in a helical circular path shaped for accelerating the flow of gas containing blood through the blood inlet channel; the blood inlet channel having an end section directed substantially tangentially into the cyclone eddy chamber spaced from the cyclone outlet;

a cyclone outlet from the cyclone eddy chamber and the blood phase axially spaced from the cyclone inlet;

the cyclone inlet and the cyclone outlet for the blood phase are arranged so that the cyclone eddy current rotates around as it moves through the cyclone eddy chamber; without reversal of its directional flow from the cyclone inlet to the cyclone outlet;

a gas outlet from the cyclone eddy chamber separated from the cyclone outlet for the blood phase for discharge of the gas phase from the cyclone eddy chamber; the gas outlet being downstream of the blood inlet channel and in the radially inner center of the cyclone eddy current path, and the gas outlet extending in a

direction which lies in the region between the axial forward direction and a tangential direction of movement of the cyclone eddy current.

4. The device of claim 3, wherein the gas outlet for the gas phase and the cyclone outlet for the blood phase are arranged coaxially, with the gas outlet within the cyclone outlet.

5. The device of claim 4, further comprising an outlet channel downstream of the cyclone outlet for the blood phase, and the gas outlet being arranged in the outlet channel following the cyclone outlet.

6. The device of claim 3, wherein the blood inlet channel is defined between a surrounding housing having an inner wall which defines an outer wall for the blood inlet channel and an insert body inserted in the surrounding housing and having an outer wall which defines an inner wall for the blood inlet channel, the housing inner wall and the insert outer wall being respectively shaped for defining the funnel shape of the blood inlet channel.

7. The device of claim 6, wherein the insert body includes at least one helically extending rib passing around the insert body; the rib, the outer wall of the insert body and the inner wall of the blood inlet channel of the housing defining a helically extending groove which defines the blood inlet channel.

8. The device of claim 7, wherein the housing inner wall maintains a substantially constant cross

section and the diameter of the insert body at the base of the groove defined between the windings of the helical rib becomes conically enlarged from a minimum diameter upstream toward the inlet of the blood inlet channel to a maximum diameter toward the downstream end of the blood inlet channel toward the cyclone eddy chamber.

9. The device of claim 7, wherein the helically extending rib is of such size and the housing is so shaped that the insert body is supported by the rib thereof on the inner housing wall.

10. The device of claim 7, wherein the insert body has an upstream end toward the inlet to the blood inlet channel and the upstream end has a central conically shaped tip which widens in the direction of flow of the blood.

11. The device of claim 10, wherein the insert body has a downstream end which narrows conically toward the cyclone eddy chamber.

12. The device of claim 7, wherein the insert body has a downstream end which narrows conically toward the cyclone eddy chamber.

13. The device of claim 7, wherein the cyclone eddy chamber and the helically shaped blood inlet channel have respective center lines which are aligned.

14. The device of claim 13, wherein the cyclone outlet for the blood phase has a center line

which is aligned with the center line of the cyclone eddy chamber.

15. The device of claim 7, wherein the cyclone eddy chamber has a cross-section which narrows in funnel like manner in the direction of flow of the blood through the cyclone eddy chamber at least towards the downstream end section of the cyclone eddy chamber.

16. The device of claim 3, wherein the cyclone eddy chamber has a cross-section which narrows in funnel like manner in the direction of flow of the blood through the cyclone eddy chamber at least towards the downstream end section of the cyclone eddy chamber.

17. The device of claim 3, further comprising a pressure supplying pump for pumping blood with positive pressure to the blood inlet channel.

METHOD AND DEVICE FOR REMOVING GAS FROM GAS-CONTAINING BLOOD

ABSTRACT OF THE DISCLOSURE

A method and device for removing gas from gas containing blood. A non-rotating cyclone eddy chamber has the blood circulating therein and centrifugal force separates the blood radially outward and the gas radially inward. The cyclone inlet comprises a blood inlet channel that extends in a helical circular form developed to narrow in funnel like manner in the direction of flow toward the cyclone eddy chamber to accelerate the blood flow entering that chamber tangentially. A gas outlet is arranged in the radially inner center of the cyclone eddy chamber path while the blood outlet is coaxial and outward of the gas outlet.

UNITED STATES OF AMERICA
COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

OFGS FILE NO.
P/619-57

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that I verily believe that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD AND DEVICE FOR REMOVING GAS FROM GAS-CONTAINING BLOOD

the specification of which is attached hereto, unless the following box is checked:

☐ was filed on _____ as United States patent Application Number or PCT International patent application number _____ and was amended on _____ (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information known to be material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code §119 of any foreign application(s) for patent or inventor's certificate or United States provisional application(s) listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign or Provisional Application(s)

COUNTRY	APPLICATION NUMBER	DATE OF FILING *(day, month, year)*	PRIORITY CLAIMED UNDER 35 U.S.C. 119
GERMANY	197 19 555.5	9 MAY 1997	YES XX NO ___
			YES ___ NO ___

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

UNITED STATES APPLICATION NUMBER	DATE OF FILING *(day, month, year)*	STATUS *(patented, pending, abandoned)*

I hereby appoint customer no. 2352 OSTROLENK, FABER, GERB & SOFFEN, LLP, and the members of the firm, Marvin C. Soffen - Reg. No. 17,542; Samuel H. Weiner - Reg. No. 18,510; Jerome M. Berliner - Reg. No. 18,653; Robert C. Faber - Reg. No. 24,322; Edward A. Meilman - Reg. No. 24,735; Stanley H. Lieberstein - Reg. No. 22,400; Steven I. Weisburd - Reg. No. 27,409; Max Moskowitz - Reg. No. 30,576; Stephen A. Soffen - Reg. No. 31,063; James A. Finder - Reg. No. 30,173; William O. Gray, III - Reg. No. 30,944 and Louis C. Dujmich - Reg. No. 30,625, as attorneys with full power of substitution and revocation to prosecute this application, to transact all business in the Patent & Trademark Office connected therewith and to receive all correspondence.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF SOLE OR FIRST INVENTOR	INVENTOR'S SIGNATURE	DATE
Alexander BROCKHOFF		Sept. 3, 1997

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FULL NAME OF THIRD JOINT INVENTOR (IF ANY)	INVENTOR'S SIGNATURE	DATE

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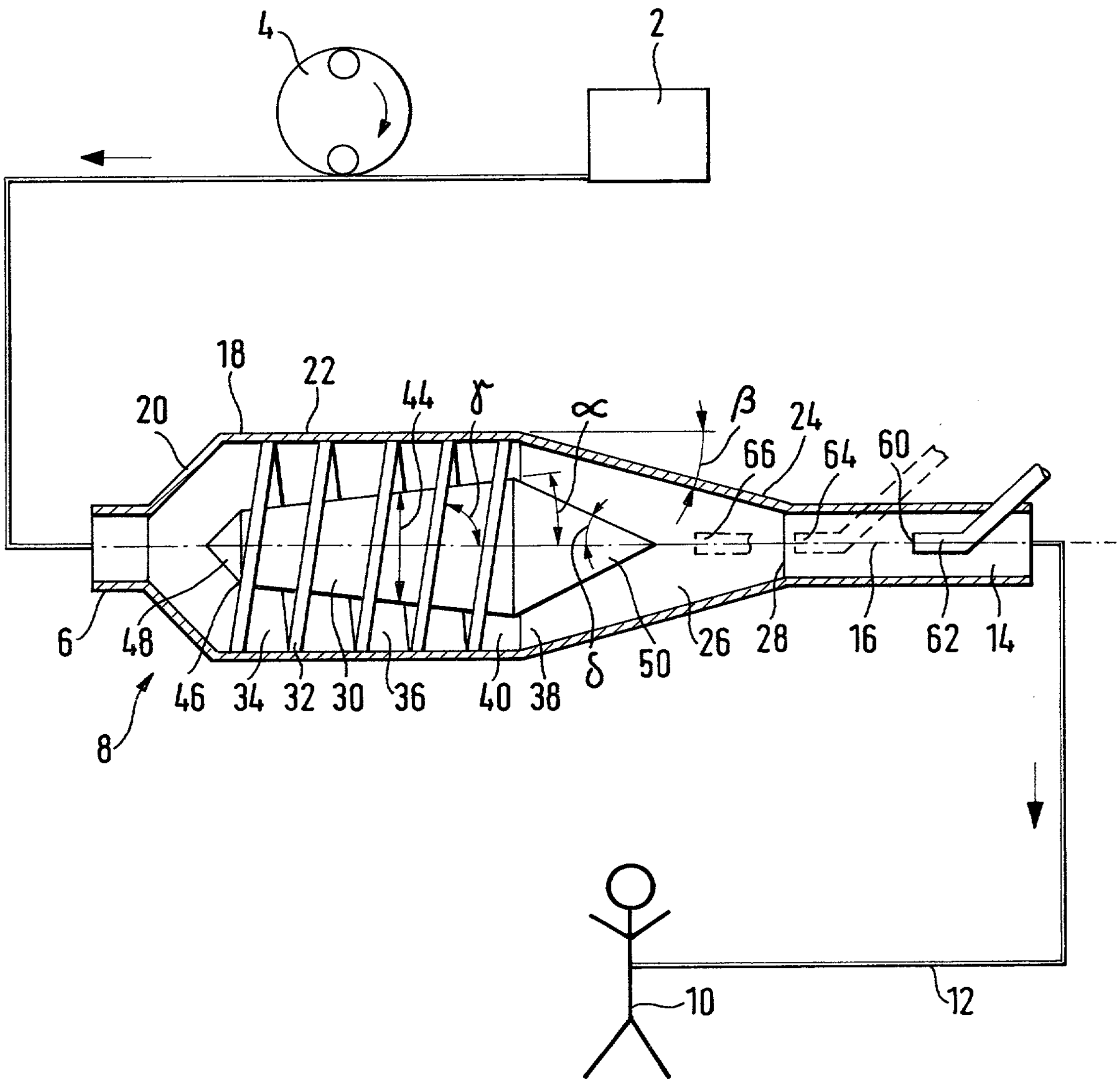
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FIG.1

Serial or Patent No.: _____ OFGS File No. P/619-57
Filing or Issue Date: _____
Applicant or Patentee: _____
For: METHOD AND DEVICE FOR REMOVING GAS FROM GAS-CONTAINING BLOOD

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
37 CFR 1.9(f) and 1.27(c) - SMALL BUSINESS CONCERN

I hereby declare that with regard to the small business concern identified below I am
[ ] the owner of the small business concern
[XX] an official of the small business concern empowered to act on behalf of same
NAME OF CONCERN: Kevin Business Corporation
ADDRESS OF CONCERN: Callee 53, Obarrio, Panama

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 1.21.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under 35 USC §41(a) and (b) in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns the affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled METHOD AND DEVICE FOR REMOVING GAS FROM GAS-CONTAINING BLOOD by inventor Alexander Brockhoff described in
[ ] U.S. Patent Application filed herewith
[ ] U.S. Patent Application Serial No. _____ filed _____
[ ] U.S. Patent No. _____ issued _____

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having the rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a non-profit organization under 37 CFR 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. 37 CFR 1.27.

NAME: _____
ADDRESS: _____
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NAME: _____
ADDRESS: _____
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I acknowledge the duty to file in this patent application or patent, notification of any change of status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 CFR 1.29(b).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC §1001, and that such willful false statements may jeopardize the validity of the patent application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Georg Vogt
ADDRESS OF PERSON SIGNING: Alte Churerstr. 36, FL-9496 Balzers

SIGNATURE: _____ **DATE:** September 3, 1997